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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
CHERNYSHEV, OLGA N	

ART UNIT	PAPER NUMBER
1649	

DATE MAILED: 04/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/796,522	PODUSLO ET AL	
	Examiner	Art Unit	
	Olga N. Chernyshev	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 February 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *31-66* is/are pending in the application.

4a) Of the above claim(s) *47 and 51-66* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *31-46 and 48-50* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *4/19/4*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I in the reply filed on February 27, 2006 is acknowledged.

Claims 1-30 have been canceled and new claims 31-66 have been added as requested in the amendment filed on February 27, 2006. Applicant submits that the claims "that read on Group I include claims 31-50 and 57-66" (section II at page 8 of the Response). Applicant further traverses the rejection on the ground(s) that claim 31 is "a generic linking claim that links all of groups I-IV (directed respectively to non-Aβ polypeptides that are antibodies, cytokines, enzymes, or leptin)" and further "because [the claims] may be properly rejoined after allowance of composition claims from which the method claims depend" (middle at page 8). Applicant's arguments have been fully considered; however, there appears to be no disagreement that claim 31 is a generic linking claim, which was properly restricted as encompassing patentably independent and distinct inventions (see reasons of record with respect to Groups I-IV in the previous office communication). An application may properly be required to be restricted to one of two or more claimed inventions if they are able to support separate patents and they are either independent (MPEP § 806.04 - § 806.04 (j)) or distinct (MPEP § 806.05 - § 806.05 (i)). Furthermore, MPEP § 803 provides that the separate classification (i.e., class and subclass) of distinct inventions is sufficient to establish a *prima facie* case that the search and examination of the plural inventions would impose a serious burden upon the Examiner; such separate classification was set forth in the Office action mailed on January 26, 2006.

Applicant's reference to MPEP 809.02(a) appears to be misplaced (top at page 9) as there is no indication in that section of MPEP that in case of linking claims the restriction requirement is waved and all the claims are examined together.

2. Applicant's request of rejoinder of the withdrawn process claims (new claims 57-66) is acknowledged. Applicant is advised that in view of the decision *In re Ochiai*, 71 F.3d 1565, PTO practice in view of that decision is directed to rejoinder of claims after allowable subject matter has been indicated, and not to withdrawal of restriction requirements.

3. The restriction requirement is still deemed proper and is therefore made FINAL.

Claims 51-66 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention. Applicant timely traversed the restriction (election) requirement in the reply filed on February 27, 2006.

4. Newly submitted claim 47 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the claim recites a composition comprising an Aβ polypeptide and a humanized antibody, wherein the originally elected invention is drawn to a composition comprising an Aβ polypeptide linked to an antibody. The new claim 47 appears to encompass a new inventive concept, which is independent and distinct from the originally presented invention.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 47 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

5. Claims 31-46 and 48-50, in so far as they are directed to a composition comprising an Aβ polypeptide linked to an antibody, are under examination in the instant office action.

Specification

6. The use of the trademarks has been noted in this application, see page 9, line 6 and page 11, line 13, for example. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Objections

7. Claims 38-40 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Claims 38-40 depend from claim 33, which is limited to an antibody, while claims 38-40 encompasses fragments of that antibody. Therefore, claims 38-40 can be infringed by a composition comprising a fragment of a monoclonal antibody, which does not infringe claim 33. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Applicant should note the "Infringement Test" for dependent claims in MPEP § 608.01(n). The test for a proper dependent claim is whether the dependent claim includes every limitation of the parent claim. A proper dependent claim shall not conceivably be infringed by anything, which would not also infringe the basic claim.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 35, 41-46 and 48 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

10. Claim 35 is vague and indefinite for recitation "specific binding affinity". Unless this limitation is positively defined, the metes and bounds of the limitation cannot be determined because it is not clear if the specific binding is limited to binding to a specific epitope, or to a protein from a particular species, or both. Clarification is required.

11. Claims 41-46 and 48 are indefinite for being dependent from indefinite claim.

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13. Claims 31-34, 42 and 43 are rejected under 35 U.S.C. 102(b) as being anticipated by Saito et al., 1995 (reference AAA of IDS submitted on April 19, 2004).

Claims 31-34, 42 and 43 are directed to a composition comprising an Aβ polypeptide of residues 1-39 of SEQ ID NO: 1 linked to a non- Aβ polypeptide. Document of Saito et al. discloses composition comprising an Aβ 1-40 peptide linked to a monoclonal antibody in a

pharmaceutically acceptable solution (see Figure 1, and pages 10227-8 specifically). Thus, Saito et al. fully anticipates the instant claims 31-34, 42 and 43.

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

15. Claim 44 is rejected under 35 U.S.C. 103(a) as being unpatentable over Saito et al., 1995.

Claim 44 is directed to an Aβ polypeptide 1-42 linked to a non- Aβ-polypeptide. Document of Saito et al. discloses an Aβ polypeptide 1-40 linked to a non- Aβ-polypeptide, a monoclonal antibody. Saito et al. do not expressly describe Aβ 1-42 chimeric molecule. At the time the invention was made, it would have been *prima facie* obvious to a person of ordinary skill in the art to use Aβ 1-42 polypeptide to construct the molecule as disclosed by Saito et al. because it is well-known in the art and also specifically explained in the article of Saito et al. (see p.10227, first column) that most common naturally occurring Aβ peptides are 40, 42 and 43 amino acids long. Therefore, one of or ordinary skill in the art would have been motivated to do so because Saito et al. explained the construct and delivery of Aβ 1-40 molecule to the brain, such molecule could be easily substituted with any other naturally occurring Aβ peptide, like 1-42.

16. Claims 36-40 and 49-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Saito et al. as applied to claims 31-34, 42 and 43 above, and further in view of Solomon et al., 1999 (WO 99/60024).

Claims 36-40 and 49-50 are directed to compositions comprising Aβ polypeptide linked to an antibody, wherein the antibody is chimeric, humanized, represented by fragments and labeled. Document of Saito et al. teaches Aβ polypeptide linked to an antibody; however, does not expressly disclose modified and labeled antibodies as recited in claims 36-40 and 49-50. The art of modifying antibodies for clinical and immunohistochemical purposes is old and well described. For example, Solomon et al. teach immunoglobulin polypeptides, which are antibody fragments, single chain fragments and chimeric antibodies and explain the advantages of using these fragments as well as modified antibodies for clinical purposes (pages 9-11). The same

document explains the old and well-known art of labeling of antibodies for diagnostic and research purposes (pages 11-12). Thus, at the time the instant invention was made, it would have been obvious to a person of ordinary skill in the art to modify chimeric polypeptide of Saito et al. to include fragments or chimeric antibodies in the construct, or to label the antibody. One would have been motivated to do this because advantages of using different modification of antibodies are well known are well described in the art, such as, for example, in publication of Solomon et al.

17. Claim 41 is rejected under 35 U.S.C. 103(a) as being unpatentable over Saito et al. as applied to claims 31-34 and 42-43 above, and further in view of US Patent 5,670,477, ('477 patent), Poduslo et al., 1997, reference AC of IDS submitted on April 19, 2004.

Claim 41 recites an Aβ polypeptide linked to an antibody, which is polyamine modified. Document of Saito et al. discloses an Aβ polypeptide linked to a non- Aβ-polypeptide, a monoclonal antibody. Saito et al. do not expressly describe linking of an antibody to polyamine. '477 patent discloses modification of a compound by conjugating it to polyamine (see claims 1 and the whole document). At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to conjugate a molecule intended for delivery through blood-brain-barrier to a polyamine as disclosed in '477 patent. One of or ordinary skill in the art would have been motivated to do so because '477 patent specifically teaches the advantages of linking polyamine to a compound to be delivered to the brain.

Conclusion

18. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (571) 272-0870. The examiner can normally be reached on 8:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet L. Andres can be reached on (571) 272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Olga N. Chernyshev, Ph.D.
Primary Examiner
Art Unit 1649

April 25, 2006